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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JAN ZAVADA, SILVIA PASTOREKOVA, and
IAROMIR PASTOREK

Appeal 2008-005832
Application 09/807,949
Technology Center 1600

Decided: August 20, 2009

Before DEMETRA J. MILLS, RICHARD M. LEBOVITZ, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for lack of written description and new matter. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF CASE

The following claim is representative.

31. A method of identifying an organic or an inorganic molecule that binds specifically to MN's cell adhesion site, to which site vertebrate cells adhere in a cell adhesion assay, wherein said site is within MN's proteoglycan-like domain, wherein said site's amino acid sequence comprises an amino acid sequence selected from the group consisting of SEQ ID NOS: 10 and 98-103, said method comprising testing an organic or an inorganic molecule in a cell adhesion assay, wherein said cell adhesion assay comprises:

(a) allowing MN protein, which comprises said site, and/or MN polypeptide, which comprises said site, to bind to a substrate, to which substrate vertebrate cells do not bind;

(b) rinsing unbound MN protein or unbound MN polypeptide from said substrate;

(c) incubating the bound MN protein or the bound MN polypeptide with said organic or inorganic molecule, and with said vertebrate cells;

(d) rinsing unbound vertebrate cells from said bound MN protein or bound MN polypeptide; and

(e) if said organic or said inorganic molecule inhibits the adhesion of said vertebrate cells to said MN protein or to said MN polypeptide identifying said molecule as specifically binding to said site;

wherein said site, and said MN protein or said MN polypeptide, are specifically bound by the M75 monoclonal antibody that is secreted from the hybridoma VU-M75, which was deposited at the American Type Culture Collection under ATCC No. HB 11128, and wherein said MN protein or said MN polypeptide is encoded by a nucleotide sequence selected from the group consisting of:

(i) SEQ ID NO: 1;

(ii) nucleotide sequences that hybridize specifically under stringent hybridization conditions of 0.02 M to 0.15 M NaCl at temperatures of 50°C to 70°C to the complement of SEQ ID No: 1; and

(iii) nucleotide sequences that differ from SEQ ID NO: 1 or from the nucleotide sequences of (ii) in codon sequence due to the degeneracy of the genetic code;

and wherein if said MN protein or said MN polypeptide is a fusion protein or a fusion polypeptide, the non-MN portion of said fusion protein or said fusion polypeptide does not contain a cell adhesion site.

Cited References

Zavada et al., *Transient transformation of mammalian cells by MN protein, a tumor-associated cell adhesion molecule with carbonic anhydrase activity*, 10 INT. J. ONCOLOGY 857-863 (1997).

Grounds of Rejection

1. Claims 31-37, 39 and 41-42 are rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement.

2. Claims 31-37, 39 and 41-42 are rejected under 35 U.S.C. § 112, first paragraph, for new matter.

ISSUE

The Issues are: Have Appellants demonstrated error in the Examiner's written description rejection? Is Appellants' negative proviso supported by the Specification, as filed?

FINDINGS OF FACT

Written Description

1. The Examiner finds that the

> written description in this case has only set forth a peptide sequence which consists of or comprises the sequence of SEQ ID No: 50 or the sequence of 10 and 98-103, and therefore the written description is not commensurate in scope to the claims that read on a peptide sequence which consists of or comprises a sequence of SEQ ID No: 1, 10, or 98-103 as claimed.

(Ans. 3.)

2. The Examiner finds that the "claims recite 'an amino acid sequence' of any one of SEQ ID No: 50, 10, or 98-10 as part of the invention. This reads on a fragment as small as two amino acid found within the sequence of SEQ ID No: 50, 10, or 98-103." (*Id.*)
3. The Examiner finds that "there does not appear to be an adequate written description in the specification as-filed that is representative of the fragment as small as two amino acid sequences derived from SEQ ID No: 50, 10, or 98-103, which is encompassed by the claimed peptide sequences." (*Id.*)
4. The Examiner finds that Appellants do not "appear to have reduced to practice the broad genus of 'an amino acid sequence' derived from either SEQ ID No: 50, 10, or 98-103." (*Id.* at 4.)
5. The Examiner finds that Appellants have not

> provided a sufficient written description of any particular structure of "an amino acid sequence" derived from SEQ ID No: 50, 10, or 98-103. "[A]n amino acid sequence" encompasses any amino acid sequence, as small as 2 amino acids, found within SEQ ID No: 50, 10, or 98-103. Thus the genus of compounds encompassed by this phrase is extensive and the artisan would not be able to recognize that Appellant was in possession of the invention as now claimed.

(*Id.*)

6. The Examiner has suggested that Appellants "may overcome this rejection by amending the claims to recite a peptide comprising 'the amino acid sequence'." (Ans. 5.)

New Matter

7. The Examiner finds that Appellants have amended the claims to include a negative proviso limitation of "the non-MN-portion of said fusion protein or said fusion polypeptide does not contain a cell adhesion site." (*Id.*)
8. The Examiner finds that "Appellant directs the examiner to page 21, lines 1-14 and page 69, lines 8-13 for support of this new limitation. However, the pages direct are drawn to the explanation of why the fusion protein would contain an additional binding site to which cells could potentially bind." (*Id.*)
9. The Examiner finds that "[t]here is no specific indication or disclosure that support a negative limitation or specific exclusion of fusion proteins missing a cell adhesion site as now currently claimed." (*Id.* at 5-6.)

PRINCIPLES OF LAW

Written Description

> The "written description" requirement . . . serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed. . . .
>
> The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.

Capon v. Eshhar, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

The Court of Appeals for the Federal Circuit has adopted the standard that

> the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002) (emphasis omitted, bracketed material in original).

New Matter

When new matter is added to the claims, the proper course of action is to reject the claims for failing to satisfy the written description requirement of §112, first paragraph. *In re Rasmussen*, 650 F.2d 1212, 1214 (CCPA 1981)("The proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure, therefore, is § 112, first paragraph ..."). The purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000). To that end, to satisfy the written description requirement, the inventor "must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). "One shows that one is 'in possession' of *the invention* by describing *the invention*, with all its claimed limitations" [emphasis in original]. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, (Fed.

Cir. 1997). It is not necessary for the specification to describe the claimed invention ipsis verbis; all that is required is that it reasonably convey to those skilled in the art that, as of the filing date sought, the inventor was in possession of the claimed invention. *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d at 1563-64; *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989); *In re Edwards*, 568 F.2d 1349, 1351-52 (CCPA 1978).

ANALYSIS

Written Description - Markush Claim

Appellants contend that formal Markush group language in claim 31 is acceptable claim language and refers only to full length amino acid sequences. (App. Br. 14.)

The Examiner argues that

> the use of the term "an" in the claim proceeds the Markush group claim language and because Markush groups are written such that each of the members of the group are in the alternative, the term "an" modifies a single sequence identifier (e.g. 10, 98,99, 100, 101, 102, or 103). Therefore, since a single sequence is being modified and because the claims is written in open/comprising language, the term "an" reads on a sequence as small as two amino acids found within any of the sequence claimed in the Markush group.

(Ans. 7.)

While such a characterization of the term "an" by the Examiner in association with a sequence might be appropriate in a claim to a single amino acid sequence (not in a Markush claim format), we do not find that

the Examiner's characterization and interpretation of the term "an" in the context of a Markush group claim to be appropriate.

An appropriate grammatical article prefacing the term "amino acid sequence" (which begins with a vowel) in the Markush group claimed is "an." In *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371-73 (Fed. Cir. 2005), the court noted the phrase "group consisting of" is a closed term, which is often used in claim drafting to signal a "Markush group" that is by its nature closed. Thus, the phrase would have been understood to define a group of specifically recited sequences from which one is to be chosen. Appellants' claim 31 recites "an amino acid sequence selected from the group consisting of SEQ ID NOS: 10 and 98-103" and thus refers to the closed group of amino acid sequences having SEQ ID NOS: 10 and 98-103, because the claim uses the Markush language "selected from the group consisting of."

CONCLUSION OF LAW

Appellants have demonstrated error in the Examiner's written description rejection. In view of the above, the Examiner's rejection of the claims for lack of written description based on improper Markush group language is reversed.

New Matter

The Examiner finds that there is no specific indication or disclosure in the Specification that supports a negative limitation or specific exclusion of fusion proteins missing a cell adhesion site as now currently claimed. (Ans. 9.)

Appellants argue that "[t]here is a clear basis in the original Specification for the proviso at issue." (App. Br. 18.) Appellants argue that the clarification of inherent characteristic does not add new matter to an application, citing *In re Smythe and Shamos*, 178 USPQ 279 (CCPA 1973). (App. Br. 17.) In this respect, Appellants argue that the Specification page 69, lines 8-13 supports the proviso of Claim 31, and "teaches that the use of the MN fusion protein GSTMN in previous experiments had masked the identification of MN's cell adhesion site and had led to incorrect conclusions, because the inventors had not realized that the 'GST [glutathione-S-transferase] anchor itself contains another binding site [to MN], which is not blocked by M75.'" (*Id.*)

> M75 is a monoclonal antibody that specifically binds MN protein at its cell adhesion site. The GST-MN fusion protein is then expressly described in the Specification as an inoperative embodiment that renders useless a cell adhesion assay to detect molecules that bind MN's cell adhesion site, in that the MN fusion protein's non-MN portion "itself contains another binding site, which is not blocked by M75." [Id.]

(*Id.*)

Appellants further argue that

> One of skill in the art would understand from the Specification that whereas Zavada et al. (1997) …taught away from the epitope for the M75 MAb being "closely related or identical" to MN's cell adhesion site, that the instant application corrected Zavada et al. (1997), and in doing so not only taught the identity of MN's cell adhesion site, but also taught that one of skill in the art must beware of a MN fusion protein/-polypeptide that contains a cell adhesion site in its non-MN portion for use in the claimed methods.

(*Id.*)

> Ones of skill in the art would then understand from the Specification that any non-MN portion of a MN fusion protein/polypeptide used in the claimed cell adhesion assays could not contain its own cell adhesion site for the cell adhesion assay to be effective to detect molecules that bind to MN's cell adhesion site. Ones of skill in the art could predict from the Specification [particularly at page 69, lines 8-13] that, if the MN fusion protein GST-MN did not work in the claimed assay because the GST portion of it contained its own binding site, then any other MN fusion protein containing a second, non-MN cell adhesion site would also not work in the claimed assay. The proviso at issue simply expresses that understanding.

(App. Br. 19.)

Appellants argue that:

> The Specification teaches that if a MN fusion protein/polypeptide is used in a MN cell adhesion assay, the non-MN portion of the fusion protein needs to be tested to assure that it does not contain a cell binding site. By the addition of the proviso to the end of Claim 31, Appellants are only making explicit what one of skill in the art would understand from the implicit teachings of the Specification: that an MN fusion protein containing a second, non-MN protein-derived cell adhesion site would not be useful to screen for molecules that bind to MN's cell adhesion site.
>
> Misconceptions concerning the identity of MN's binding site in Zavada et al., Int. J. Oncol., 10: 857 (1997) … arose from the nature of the MN-GST fusion protein used. The Specification corrects the misconceptions concerning the identity of MN's binding site in Zavada et al. (1997). For example, the Specification at page 69, lines 8-13 reads:
>
> > There can be no doubt on the specificity of cell attachment to purified MN/CA IX+. It is abrogated by specific MAb M75, at a dilution 1:1000 of ascites fluid. This is a correction to our previous report in Zavada et al.

(App. Br. 19-20.)

We find Appellants have the better argument and that the negative proviso in claim 31 is supported by the original disclosure when it is read by one of ordinary skill in the art. The Examiner has not shown that one of ordinary skill in the art would not have understood the disclosure's meaning consistent with that put forth by Appellants.

CONCLUSION OF LAW

Appellants' negative proviso is supported by the Specification as filed. The new matter rejection is reversed.

SUMMARY

The written description and new matter rejections are reversed.

REVERSED

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